IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES OF AMERICA,
Plaintiff,

ex rel. REDACTED

Plaintiff-Relator

v.

TEXAS ONCOLOGY, P.A.

Defendant.

C.A. No. 3:18-CV-1865-L

FILED *IN CAMERA* AND UNDER SEAL PURSUANT TO 31 U.S.C. §3730(b)(2)

FIRST AMENDED COMPLAINT
(Jury Trial Demanded)

Relator REDACTED, for [Relator's] complaint against Texas Oncology, P.A., alleges as follows:

1. This action is brought on behalf of Relator and the United States pursuant to the False Claims Act, 31 U.S.C. sections 3729, *et seq.* and the Stark Law, 42 U.S.C. § 1395nn, et seq.

2. This action concerns violations of the Stark Law.

I. JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732.

4. This Court has personal jurisdiction and venue over Defendant pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a). Jurisdiction is proper over the Defendant

because the Defendant can be found in, reside in, and/or have transacted business within this Court's jurisdiction, and some of the acts in violation of 31 U.S.C. § 3729 occurred within this district.

5. In addition, this Court has jurisdiction under the doctrine of supplemental jurisdiction over the state law claims pleaded or which may be pleaded to the extent that these claims arise out of a common nucleus of operative facts under 28 U.S.C. §1367(a).

6. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 (b) & (c) and 31 U.S.C. § 3732(a) because at least one Defendant resides in or transact business in this district and because a substantial portion of the events or omissions giving rise to the claims alleged herein occurred in this district. Relator is familiar with Defendant's fraudulent billing practices alleged in this Complaint and is aware that the pervasive misconduct at issue occurred in this District.

7. This case is not based on a public disclosure within the meaning of the FCA, and Relator is the original source of the allegations contained herein. Relator has direct and independent knowledge of the alleged fraud and disclosed this information to the government before filing suit, pursuant to 31 U.S.C. § 3730(e)(4)(B). Relator believes that there has been no public disclosure of these allegations and transactions such that subparagraph (e)(4) does not apply and this disclosure was not necessary. However, as a precautionary measure, in the event there has been a public disclosure, Relator made a pre-complaint disclosure in order to qualify as an "original source" under subparagraph (e)(4)(B)(2). Relator has knowledge that is independent of, and materially

adds to, any publicly disclosed allegations or transactions, and voluntarily provided the information to the Government before filing [Relator's] False Claims Act complaint.

II. PARTIES

8. Relator REDACTED, is an individual citizen of REDACTED, currently residing in REDACTED. At all relevant times, [Relator] was a citizen of REDACTED and a resident of REDACTED.

9. Defendant, Texas Oncology, P.A., is a Professional Association registered and doing business in Texas. Its corporate office is in Dallas County at 12221 Merit Drive, Dallas, TX 75251. Its registered agent for service (and treasurer) is John Sims, 12221 Merit Drive, Dallas, TX 75251. Other officers include: R. Steven Paulson (president), Fred Ekery (vice president) and Charles S. White III (secretary).

III. FACTS

10. [Relator] began working for Defendant, Texas Oncology, P.A. ("Texas Oncology" or "TOPA"), on REDACTED. [Relator] was terminated on REDACTED. [Relator's] exit agreement stated that REDACTED. [Relator] was REDACTED.

11. Relator currently works as REDACTED.

12. Texas Oncology has more than 175 cancer treatment centers throughout Texas and southeastern Oklahoma. It is a subsidiary of U.S. Oncology, a network of more than 1,400 physicians and 400 treatment locations throughout the United States. Texas Oncology, as part of the U.S. Oncology network, is controlled by the network's governing board. U.S. Oncology is wholly owned by McKesson Corporation, which acquired U.S. Oncology in 2010.

13. Texas Oncology's Abilene location operated under the assumed name of "Texas Cancer Center of Abilene."

14. In addition to employing oncologists, the Texas Cancer Center of Abilene ("TCC Abilene") also provided in-office ancillary services to patients, including radiology and other imaging services.

15. Texas Oncology had a policy whereby its physicians ensured that all of their patients used Texas Oncology's in-office radiology and imaging services, in order to maximize Texas Oncology's profits.

16. Relator and five other Abilene physicians practicing at Texas Oncology's TCC Abilene location followed Texas Oncology's policy and referred all patients to obtain radiology and other imaging services from TCC Abilene, without considering other local providers of radiology and imaging services.

17. These referrals were made on a daily basis while Relator worked for Texas Oncology, (from REDACTED through REDACTED) and upon information were also made before and after Relator was employed by Texas Oncology.

18. There were other imaging centers within 25 miles of TCC Abilene's location, including: Medical Diagnostic Imaging, 4349 S. Treadaway Blvd, Abilene Texas, 79602, and Radiology Associates 401 Cypress St. #110, Abilene, TX 79601. These were never disclosed to TCC Abilene's patients, in violation of the Stark Law.

19. Relator has reason to believe these Stark Law violations were not limited to the TCC Abilene location. All policies at the TCC Abilene location emanated from Texas Oncology's headquarters in Dallas. Accordingly, it stands to reason that if the

self-referral rule was being violated at the TCC Abilene location, it was being violated at Texas Oncology's other locations as well.

20. More than 50% of Texas Oncology's patients were covered by Medicare, Medicaid or Tricare.

21. Federal regulations prohibit referrals by physicians to DHS-furnishing entities that are commonly owned. 42 CFR § 411.353(b) provides that,

> "[a]n entity that furnishes DHS[1] pursuant to a referral that is prohibited by paragraph (a) of this section may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payer, or other entity for the DHS performed pursuant to the prohibited referral."

22. The Stark Law, which generally prohibits self-referrals, permits physicians to refer patients to their in-house radiology and imaging departments, but requires that physicians making these self-referrals disclose to patients other providers that the patients could use for those services. 42 CFR § 411.355(b) creates an "In-Office Ancillary Services" exception to the Stark Law provision, stating that the self-referral prohibition of §411.353 does not apply to in-office ancillary services that meet seven individual conditions. The seventh "Notice of Other Suppliers" condition states:

> (i) With respect to magnetic resonance imaging, computed tomography, and positron emission tomography services identified as "radiology and certain other imaging services" on the List of CPT/HCPCS Codes, the referring physician must provide written notice to the patient at the time of the referral that the patient may receive the same services from a person other than one described in paragraph (b)(1) of this section. Except as set forth in paragraph (b)(7)(ii) of this section, the written notice must include a list of at least 5 other suppliers (as defined in § 400.202 of this chapter) that provide the services for which the individual is being referred and

[1] DHS is a "designated health service" which includes imaging.

> which are located within a 25-mile radius of the referring physician's office location at the time of the referral. The notice should be written in a manner sufficient to be reasonably understood by all patients and should include for each supplier on the list, at a minimum, the supplier's name, address, and telephone number.
>
> (ii) If there are fewer than 5 other suppliers located within a 25-mile radius of the physician's office location at the time of the referral, the physician must list all of the other suppliers of the imaging service that are present within a 25-mile radius of the referring physician's office location. Provision of the written list of alternate suppliers will not be required if no other suppliers provide the services for which the individual is being referred within the 25-mile radius.

42 CFR § 411.355(b)(7).

23. Because Defendant never complied with this "Notice of Other Suppliers" provision, the In-Office Ancillary Services exception does not apply, and Defendant violated the 42 CFR § 411.353 self-referral prohibition, and thus violated the Stark Law.

IV. STARK LAW VIOLATIONS

24. The Stark Law prohibits physicians and certain other entities providing healthcare items and services from submitting Medicare claims for payment for items and services that are the product of patient referrals from physicians having an impermissible "financial relationship" (as defined in the statute) with the physicians. *See* 42 U.S.C. § 1395nn.

25. The Stark Law requires that the Medicare program deny payment for claims for any services billed in violation of its provisions. 42 U.S. C. § 1395nn(g). In addition, it requires that providers who have collected Medicare payments for a healthcare service "performed under a prohibited referral must refund all collected amounts on a timely basis." 42 C.F.R. § 411.353. The Stark Law is also applicable to Medicaid claims. 42 U.S.C. §1396b(s).

26. The Stark Law establishes the presumptive rule that providers may not bill, and the Medicare program will not pay for, designated health services (as defined in the statute) generated by a referral from a physician with whom the provider has a financial relationship. 42 U.S.C. §§ 1395nn(a)(1), and (g)(1).

27. Congress enacted the Stark Law in 1989 because it found that financial relationships between physicians and entities to whom they refer patients can compromise the physicians' professional judgment as to whether an item or service is medically necessary, safe, effective, and of good quality. It applies to multiple types of Designated Health Services ("DHS") including imaging services.

28. Congress relied upon various academic studies consistently showing that physicians who had financial relationships with entities to which they referred used more of those entities' services than similarly situated physicians who did not have such relationships. The Stark Law was designed to protect the taxpayer from paying for the costs of questionable utilization of services by removing monetary influences on referral decisions.

29. At all times relevant to this Complaint, the Stark Law has applied to payments for imaging services and the resulting claims to the Medicare program.

30. The Stark Law, 42 U.S.C. §1395nn(a)(1), provides:

(a) Prohibition of certain referrals

(1) In general. Except as provided in subsection (b) of this section, if a physician . . . has a financial relationship with an entity specified in paragraph (2), then—

(A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and

(B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for

designated health services furnished pursuant to a referral prohibited under subparagraph (A).

31. As stated above, federal regulations prohibit referrals by physicians to imaging facilities that are commonly owned. 42 CFR § 411.353(b).

32. Although physicians may refer patients to their in-house radiology and imaging departments, they must disclose to patients other providers that the patients could use for those services. 42 CFR § 411.355(b) (the "In-Office Ancillary Services" exception.) The self-referral prohibition of §411.353 does not apply to in-office ancillary services that meet seven individual conditions. As stated above, Defendant failed to comply with the "Notice of Other Suppliers" condition set forth in 42 CFR § 411.355(b)(7).

33. Because Defendant never complied with this "Notice of Other Suppliers" provision, the In-Office Ancillary Services exception does not apply, and Defendant violated the 42 CFR § 411.353 self-referral prohibition, and thus violated the Stark Law.

V. THE MEDICARE PROGRAM

34. In 1965, Congress passed Title XVIII of the Social Security Act to pay for certain healthcare services for eligible individuals. 42 U.S.C. §§ 1395 *et seq.* Medicare Part A covers hospitalization costs, services rendered by skilled nursing facilities, home health care, and hospice care, while Part B covers physician services, outpatient care, and other miscellaneous services. *See* 42 U.S.C. §§ 1395j-1395w-4.

35. The U.S. Department of Health and Human Services ("HHS") is a federal agency whose activities, operations, and contracts are paid from federal funds. The Center for Medicare and Medicaid Services ("CMS") is a division of HHS that

administers the Medicare program. To administer Medicare reimbursement claims, HHS contracts with private local insurance companies, known as "carriers" and "fiscal intermediaries," to review and pay appropriate reimbursement claims related to services provided to Medicare beneficiaries. *See* 42 U.S.C. § 1395u. Providers such as Defendant are legally obligated to familiarize themselves with Medicare's reimbursement rules, including those set forth in the Medicare Manuals. *Heckler v. Cmty. Health Serv. of Crawford County, Inc.,* 467 U.S. 51, 64-65 (1984).

36. The Secretary of HHS has broad statutory authority to "prescribe such regulations as may be necessary to carry out the administration of the [Medicare] insurance programs ..." 42 U.S.C. §1395hh(a)(1). In addition to promulgating regulations, the Secretary has the power to formulate rules for the administration of the Medicare programs, through the issuance of manual instructions, interpretive rules, statements of policy, and guidelines of general applicability. 42 U.S.C. §1395hh(c)(1).

37. To submit Medicare reimbursement claims, providers submit an Electronic Data Interchange Enrollment Form which contains several provisions, including one that states: "anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other information relating to that claim that is required pursuant to this Agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law." Medicare only pays for services that are "reasonable and necessary for the diagnosis or treatment of illness or injuy." 42 U.S.C. § 1395y(a)(l)(A). It is illegal to provide and bill for medically unnecessary services and equipment. Seeking payment for medically unnecessary services is an act designed to obtain

reimbursement for a service that is not warranted by the patient's current and documented medical condition.

VI. THE FALSE CLAIMS ACT

38. The False Claims Act provides, *inter alia*, that any person who--

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G); . . . or
>
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-4101), plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C.A. § 3729 (a)(1)(A-G).

39. The term "claim" includes "any request or demand, whether under a contract or otherwise, for money . . . that—

> (i) is presented to an officer, employee, or agent of the United States; or
>
> (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government--
>
> (I) provides or has provided any portion of the money or property requested or demanded; or

> (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded . . .

31 U.S.C.A. § 3729 (a)(2).

40. Any person who knowingly submits a false or fraudulent claim to the Government for payment or approval (or to a contractor if the money is to be spent on the Government's behalf or to advance a Government program and the Government provides any portion of the money requested or demanded) is liable to the Government for a civil penalty for each claim between $5,500 and $11,000 for conduct on or before November 2, 2015, and between $10,781 and $21,563 for conduct after November 2, 2015, and between $10,957 and $21,916 for penalties assessed after February 3, 2017, plus three times the actual damages that the Government sustained. 31 U.S.C. § 3729(a). The Act permits assessment of the civil penalty even without proof of specific damages.

41. The FCA defines a "claim" for payment to include "any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded." 31 U.S.C. § 3729(c). Accordingly, pursuant to the express language of the FCA and the statutory definition of "claim," Medicaid claims submitted to state Medicaid agencies are considered to be claims presented to the federal government, and thus may give rise to liability under the FCA.

VII. CAUSES OF ACTION

COUNT ONE

FALSE CLAIMS ACT, 31 U.S.C. §3729(a)(1)(A) STARK LAW VIOLATIONS, 42 U.S.C. § 1395nn

42. All paragraphs of this Complaint are incorporated herein by reference.

43. The Stark Law requires that the Medicare program deny payment for these claims because they were billed in violation of its provisions. 42 U.S. C. § 1395nn(g).

44. The Stark law also requires that Defendant, which has collected Medicare payments for a healthcare service "performed under a prohibited referral must refund all collected amounts on a timely basis." 42 C.F.R. § 411.353. The Stark Law is also applicable to Medicaid claims. 42 U.S.C. §1396b(s).

45. Accordingly, the United States is entitled to refund of all amounts paid to Defendant for imaging services for Defendant's patients, trebled under the False Claims Act.

PRAYER

WHEREFORE, Relator prays for the following relief for [Relator's] FCA claims:

1. A permanent injunction requiring Defendant to cease and desist from violating the federal FCA and the Stark law;

2. Judgment against Defendant in an amount equal to three times the amount of damages the United States has sustained as a result of the Defendant's unlawful conduct;

3. Civil monetary penalties for each false and fraudulent claim submitted to the United States by Defendant, as permitted by 31 U.S.C. § 3729, and as adjusted pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461, 64 Fed. Reg. 47099, 47103 (1999), or otherwise (currently, between $5,500 and $11,000 for conduct on or before November 2, 2015, and between $10,781 and $21,563 for conduct after November 2, 2015, and between $10,957 and $21,916 for penalties assessed after February 3, 2017.)

4. An award to Relator pursuant to 31 U.S.C. §3730(d) of reasonable attorneys' fees, costs, and expenses;

5. Such other relief as the Court deems just and equitable.

VIII. JURY DEMAND

Relator hereby demands a trial by jury.

Dated: March 26, 2019

Respectfully submitted,

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